Interview Summary	Application No.	Applicant(s)	
	10/054,611	CECH ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Malgorzata A. Walicka*. (3)*Michael Schiff*.

(2) *Rebecca Prouty*. (4)_____.

Date of Interview: *26 May 2005*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: *1-9,13-16,27,35,39-41,43,45 and 46*.

Identification of prior art discussed: *none*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *The amendment of the draft faxed to the examiner on May 4, 2005 was discussed. The minor issues marked in the attached draft of the claims prevent the allowance of the case. The issues will be addressed by the Applicants*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

05/26/05
Examiner's signature, if required

Methods for Detecting Nucleic Acids Encoding Human Telomerase Reverse Transcriptase

USSN 10/054,611
018/182c
(May 9/97 disclosure)

Claims

1. *(Currently Amended)* A method of identifying a nucleic acid that encodes human telomerase reverse transcriptase (hTRT) or fragment thereof in a sample, comprising:
   a) combining the sample with a polynucleotide probe such that the probe hybridizes specifically to the nucleic acid if the nucleic acid encodes hTRT or fragment thereof;
   b) detecting any hybrid formed as a result of a); and
   c) identifying the nucleic acid as encoding hTRT or fragment thereof if the hybrid is detected;
   wherein the probe hybridizes specifically to a DNA having the sequence of the hTRT encoding region of SEQ. ID NO:224 at 5°C to 25°C below T_m in aqueous solution at 1 M NaCl , but does not hybridize to a DNA having the sequence of SEQ. ID NO:62 under the same reaction conditions;
   wherein T_m is the melting temperature of double-stranded DNA having the sequence of said encoding region under the same reaction conditions.

2. *(Currently Amended)* A method of detecting a nucleic acid that encodes hTRT or fragment thereof in a sample, comprising:
   a) combining the sample with a polynucleotide probe such that the probe hybridizes specifically to a nucleic acid comprising at least 100 consecutive nucleotides contained in SEQ ID NO:224 if present in the sample;
   b) detecting any hybrid formed as a result of a); and
   c) identifying the nucleic acid as encoding hTRT or fragment thereof if the hybrid is detected;
   wherein the polynucleotide probe consists essentially of a sequence identical or complementary to 25 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224 that are not contained in SEQ. ID NO:62.

3. *(Original)* The method of claim 2, wherein the hTRT nucleic acid is human genomic DNA.

4. *(Previously presented)* The method of claim 2, wherein the hTRT nucleic acid is mRNA or cDNA.

5. *(Previously presented)* The method of claim 2, wherein the hTRT nucleic acid consists essentially of 250 or more nucleotides of SEQ ID NO:224.

6. *(Previously presented)* The method of claim 2, wherein the hTRT nucleic acid consists essentially of 500 or more nucleotides of SEQ ID NO:224.

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7. *(Previously presented)* The method of claim 2, wherein the probe consists essentially of a sequence identical or complementary to 30 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224.

8. *(Previously presented)* The method of claim 2, wherein the probe consists essentially of a sequence identical or complementary to 50 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224.

9. *(Previously presented)* The method of claim 2, wherein the probe consists essentially of a sequence identical or complementary to 100 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224.

10 to 12. *CANCELLED*

13. *(Currently Amended)* A method of identifying a nucleic acid that encodes hTRT or fragment thereof in a sample, comprising:

a) combining the sample with a polynucleotide primer under conditions that the primer specifically primes amplification of SEQ. ID NO:224 or fragment thereof if present in the sample;

b) detecting any amplification product formed as a result of a); and

c) identifying the nucleic acid as encoding hTRT or fragment thereof if the amplification product is detected;

wherein the primer hybridizes specifically to a DNA having the sequence of the hTRT encoding region of SEQ. ID NO:224 at 5°C to 25°C below T_m in aqueous solution at 1 M NaCl , but does not hybridize to a DNA having the sequence of SEQ. ID NO:62 under the same reaction conditions;

wherein T_m is the melting temperature of double-stranded DNA having the sequence of said encoding region under the same reaction conditions.

14. *(Currently Amended)* A method of detecting a nucleic acid encoding hTRT or fragment thereof in a sample, comprising:

a) combining the sample with polynucleotide primers so as to prime amplification of nucleic acid encoding hTRT or fragment thereof if present in the sample;

b) detecting any amplified product formed as a result of a); and

c) identifying the nucleic acid as encoding hTRT or fragment thereof if the amplification product is detected;

wherein each of said primers consists essentially of a sequence identical or complementary to 15 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224 , but at least one of the primers does not consist of a sequence identical or complementary to 15 or more consecutive nucleotides from SEQ. ID NO:62.

15. *(Previously presented)* The method of claim 14, wherein each of said primers consists essentially of a sequence identical or complementary to 30 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224.

16. *(Previously presented)* The method of claim 14, wherein each of said primers consists essentially of a sequence identical or complementary to 50 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224.

17 to 22. *CANCELLED*

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23. *(Withdrawn)* A combination of oligonucleotide primers for PCR amplification for use in detecting an hTRT nucleic acid according to claim 14, wherein each primer consists essentially of a sequence identical or complementary to 15 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224.

24. *(Withdrawn)* The combination of primers of claim 23, wherein each primer consists of 15-30 nucleotides.

25. *(Withdrawn)* The combination of primers of claim 23, wherein each primer consists of 20-25 nucleotides.

26 to 34. *CANCELLED*

35. *(Previously presented)* The method of claim 1, wherein a) comprises combining the sample with the probe at 5°C to 25°C below T_m in aqueous solution at 1 M NaCl.

36. *CANCELLED*

37. *(Previously presented)* The method of claim 1, wherein the probe comprises a sequence identical or complementary to 100 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224.

38. *CANCELLED.*

39. *(Previously presented)* The method of claim 1, wherein the sample has been taken from a patient having a tumor.

40. *(Previously presented)* The method of claim 2, wherein the sample has been taken from a patient having a tumor.

41. *(Previously presented)* The method of claim 13, wherein a) comprises combining the sample with the primer at 5°C to 25°C below T_m in aqueous solution at 1 M NaCl.

42. *CANCELLED.*

43. *(Previously presented)* The method of claim 13, wherein the primer comprises a sequence identical or complementary to 30 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224.

44. *CANCELLED*

45. *(Previously presented)* The method of claim 13, wherein the sample has been taken from a patient having a tumor.

46. *(Previously presented)* The method of claim 14, wherein the sample has been taken from a patient having a tumor.

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47. *(New)* A method of identifying a nucleic acid that encodes human telomerase reverse transcriptase (hTRT) or fragment thereof in a sample, comprising:

a) combining the sample with a polynucleotide probe such that the probe hybridizes specifically to the nucleic acid if the nucleic acid encodes hTRT or fragment thereof;

b) detecting any hybrid formed as a result of a); and

c) identifying the nucleic acid as encoding hTRT or fragment thereof if the hybrid is detected;

wherein the probe hybridizes specifically to a DNA having a sequence consisting of SEQ. ID NO:62 at 5°C to 25°C below T_m in aqueous solution at 1 M NaCl;

wherein T_m is the melting temperature of double-stranded DNA having the sequence of said encoding region under the same reaction conditions.

SEQ ID NO:62

48. *(New)* The method of claim 47, wherein a) comprises combining the sample with the probe at 5°C to 25°C below T_m in aqueous solution at 1 M NaCl.

49. *(New)* The method of claim 47, wherein the probe comprises a sequence identical or complementary to 100 or more consecutive nucleotides from SEQ ID NO:62.

50. *(New)* The method of claim 47, wherein the sample has been taken from a patient having a tumor.

51. *(New)* A method of detecting a nucleic acid that encodes hTRT or fragment thereof in a sample, comprising:

a) combining the sample with a polynucleotide probe such that the probe hybridizes specifically to a nucleic acid comprising at least 100 consecutive nucleotides contained in SEQ ID NO:62 if present in the sample;

b) detecting any hybrid formed as a result of a); and

c) identifying the nucleic acid as encoding hTRT or fragment thereof if the hybrid is detected;

wherein the polynucleotide probe consists essentially of a sequence identical or complementary to 25 or more consecutive nucleotides from SEQ ID NO:62.

52. *(New)* The method of claim 51, wherein the probe consists essentially of a sequence identical or complementary to 30 or more consecutive nucleotides from SEQ ID NO:62.

53. *(New)* The method of claim 51, wherein the probe consists essentially of a sequence identical or complementary to 50 or more consecutive nucleotides from SEQ ID NO:62.

54. *(New)* The method of claim 51, wherein the probe consists essentially of a sequence identical or complementary to 100 or more consecutive nucleotides from SEQ ID NO:62.

55. *(New)* The method of claim 51, wherein the sample has been taken from a patient having a tumor.

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56. *(New)* A method of identifying a nucleic acid that encodes hTRT or fragment thereof in a sample, comprising:

a) combining the sample with a polynucleotide primer under conditions that the primer specifically primes amplification of SEQ. ID NO:62 or fragment thereof if present in the sample;

b) detecting any amplification product formed as a result of a); and

c) identifying the nucleic acid as encoding hTRT or fragment thereof if the amplification product is detected;

wherein the primer hybridizes specifically to a DNA having a sequence consisting of SEQ. ID NO:62 at 5°C to 25°C below T_m in aqueous solution at 1 M NaCl;

wherein T_m is the melting temperature of double-stranded DNA having the sequence of said encoding region under the same reaction conditions.

57. *(New)* The method of claim 56, wherein a) comprises combining the sample with the primer at 5°C to 25°C below T_m in aqueous solution at 1 M NaCl.

58. *(New)* The method of claim 56, wherein the primer comprises a sequence identical or complementary to 30 or more consecutive nucleotides from SEQ. ID NO:62.

59. *(New)* The method of claim 56, wherein the sample has been taken from a patient having a tumor.

60. *(New)* A method of detecting a nucleic acid encoding hTRT or fragment thereof in a sample, comprising:

a) combining the sample with polynucleotide primers so as to prime amplification of nucleic acid encoding hTRT or fragment thereof if present in the sample;

b) detecting any amplified product formed as a result of a); and

c) identifying the nucleic acid as encoding hTRT or fragment thereof if the amplification product is detected;

wherein each of said primers consists essentially of a sequence identical or complementary to 15 or more consecutive nucleotides from SEQ ID NO:62.

61. *(New)* The method of claim 60, wherein each of said primers consists essentially of a sequence identical or complementary to 30 or more consecutive nucleotides from SEQ ID NO:62.

62. *(New)* The method of claim 60, wherein each of said primers consists essentially of a sequence identical or complementary to 50 or more consecutive nucleotides from SEQ ID NO:62.

63. *(New)* A combination of oligonucleotide primers for PCR amplification for use in detecting an hTRT nucleic acid according to claim 60, wherein each primer consists essentially of a sequence identical or complementary to 15 or more consecutive nucleotides from SEQ ID NO:62.

Withdrawn

64. *(New)* The method of claim 60, wherein the sample has been taken from a patient having a tumor.

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Rejection under 35 USC § 112 ¶ 2:

Certain claims stand rejected under § 112 ¶ 2 as being indefinite. Specifically, the Office Action indicates that the meaning of the phrase "consisting essentially of" is unclear in view of the explanation given previously.

In response, applicants submit the following clarification. A nucleic acid "consisting essentially of" a particular sequence means that the nucleic acid may contain additional nucleotides or other elements, so long as the additional features do not prevent the nucleic acid from exercising the function indicated in the claims. In particular:

- Claims 2, 51, and their dependents cover the use of the nucleic acid as a probe. Any additional features of the nucleic acid (if present) do not prevent the probe from hybridizing specifically with SEQ. ID NO:224 or its complement.
- Claims 14, 60, and their dependents cover the use of the nucleic acid as an amplification primer. Any additional features of the nucleic acid (if present) do not prevent the primer from specifically amplifying the corresponding portion of SEQ. ID NO:224.

It is respectfully submitted that these claims do not need to indicate the reaction conditions of the hybridization step, because the hybridization referred to is not used to define what nucleic acid sequences are included in the claim. Instead, the nucleotides are defined explicitly in the last part of the claim, where it is stated that they have sequences that are identical or complementary to 25 or more consecutive nucleotides from the hTRT encoding region of SEQ ID NO:224. This is different from claims 1, 13, 47, and 56, where the nucleotides are defined according to their hybridization properties, and the hybridization properties are given.

Withdrawal of this rejection is respectfully requested.

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